

§ 493.1275

(c) Labeling of blood and blood products must conform to 21 CFR part 606, subpart G.

(d) Policies to ensure positive identification of a blood or blood product recipient must be established, documented, and followed.

§ 493.1275 Standard; Blood and blood products storage facilities.

(a) The blood and blood products must be stored under appropriate conditions, which include an adequate temperature alarm system that is regularly inspected.

(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period; and

(2) Inspections of the alarm system must be documented.

(b) If blood is stored or maintained for transfusion outside of a monitored refrigerator, the facility must ensure and document that storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.

§ 493.1277 Standard; Arrangement for services.

In the case of services provided outside the blood bank, the facility must have an agreement reviewed and approved by the director that governs the procurement, transfer and availability of blood and blood products.

§ 493.1279 Standard; Provision of testing.

There must be provision for prompt ABO blood group, D(Rho) type, unexpected antibody detection and compatibility testing in accordance with § 493.1269 of this subpart and for laboratory investigation of transfusion reactions, either through the facility or under arrangement with an approved facility on a continuous basis, under the supervision of a pathologist or other doctor of medicine or osteopathy meeting the qualifications of §§ 493.1449(b) or 493.1449(q).

§ 493.1283 Standard; Retention of samples of transfused blood.

According to the facility's established procedures, samples of each unit of transfused blood must be retained

42 CFR Ch. IV (10–1–99 Edition)

for further testing in the event of reactions. The facility must promptly dispose of blood not retained for further testing that has passed its expiration date.

§ 493.1285 Standard; Investigation of transfusion reactions.

The facility, according to its established procedures, must promptly investigate all transfusion reactions occurring in all facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. The facility must document that all necessary remedial actions are taken to prevent future recurrences of transfusion reactions and that all policies and procedures are reviewed to assure that they are adequate to ensure the safety of individuals being transfused within the facility.

Subpart L [Reserved]

Subpart M—Personnel for Moderate Complexity (Including the Subcategory) and High Complexity Testing

SOURCE: 57 FR 7172, Feb. 28, 1992, unless otherwise noted.

§ 493.1351 General.

This subpart consists of the personnel requirements that must be met by laboratories performing moderate complexity testing, PPM procedures, high complexity testing, or any combination of these tests.

[60 FR 20049, Apr. 24, 1995]

LABORATORIES PERFORMING PROVIDER-PERFORMED MICROSCOPY (PPM) PROCEDURES

SOURCE: 60 FR 20049, Apr. 24, 1995, unless otherwise noted.

§ 493.1353 Scope.

In accordance with § 493.19(b), the moderate complexity procedures specified as PPM procedures are considered such only when personally performed